REMARKS

Claims 46 – 48, 50 – 52, 54 – 59 and 61 – 67 are pending in this application.

Claims 46 – 69 have been rejected.

Claims 46 and 58 are currently amended.

Claims 49, 53, 60, 68 and 69 have been canceled.

Amendments to the Specification

The paragraph beginning at line 13 of page 10 has been amended to disclose that cancer is treated with a wholly implantable medical device which is operable to deliver electroporation therapy. This amendment is supported in Figures 2 and 6. No new matter has been added.

The paragraph beginning at line 4 of page 11 has been amended to disclose that the implantable medical device is a wholly implantable electroporation device. This amendment is supported in Figures 2 and 6 and throughout the specification. No new matter has been added.

The paragraph beginning at line 10 of page 11 has been amended to disclose that first lead 202 may be wholly implantable. This amendment is supported in Figures 2 and 6. No new matter has been added.

The paragraph beginning at line 11 of page 12 has been amended to disclose that the logic and control circuitry may be contained within the housing. This amendment is supported in Figure 3. No new matter has been added.

The paragraph beginning at line 16 of page 13 has been amended to disclose that the implantable medical device is wholly implantable, and that the reservoir may be contained within the housing. This amendment is supported in Figures 2 and 3. No new matter has been added.

The paragraph beginning at line 24 of page 13 has been amended to disclose that the sensor transmits a biological parameter to the logical and operative control circuitry.

This amendment is supported by the originally filed claim 3 and throughout the specification. No new matter has been added.

Amendments to the Claims

Claims 46 and 58 have been amended to clarify the claims by correcting errors in antecedent basis with the phrase "at least one electrical pulse" at lines 10 – 11 of claim 46 and lines 13 – 14 of claim 58. Claims 46 and 58 have been further clarified by adding the inadvertently omitted word "strength" to the phrase "field strength" at line 11 of claim 46 and line 14 of claim 58. Claims 46 and 58 have been further clarified to correct a typographical error by changing the abbreviation "ms" to "microseconds". These amendments correct errors in form. No new matter has been added.

Claims 46 and 58 have been further amended to incorporate the subject matter of claims 49 and 60, respectively, which have been canceled. No new matter has been added.

Claim 46 has been further clarified by removing a redundant reference in the preamble to an implantable medical device. No new matter has been added.

Claim 58 has been further clarified by inserting the inadvertently omitted word "a" before "a wholly-implantable electroproration device" at line 2. Claim 58 has been further amended to correct an error in antecedent basis with the phrase "at least one wholly-implantable therapy electrode" at lines 4 – 6. These amendments correct errors in form. No new matter has been added.

Claims 53, 68 and 69 have been canceled.

Objections to the Specification

The specification has been objected to as failing to provide proper antecedent basis for the claimed subject matter. It is respectfully submitted that the grounds for these objections have been cured and that the objections should be withdrawn.

The specification was objected to for failing to disclose a method for treating a cancerous tumor via a wholly-implantable medial device and implanting an electroporation device wholly within a body. As described above, claim 46 has been amended to eliminate the redundant reference to the implantable medical device. Further, the paragraph beginning at line 4 of page 11 has been amended to recite that the electroporation device is implanted wholly within a body. Thus, it is respectfully submitted that the grounds for this objection have been cured and that the objection should be withdrawn.

The specification was objected to for failing to disclose a wholly implantable medical device which includes a drug reservoir and operative control circuitry both disposed within a housing for the device. As noted above, the paragraph beginning at line 16 of page 13 has been amended to recite that the implantable medical device 200 is wholly implantable. The implantable medical device is disclosed in the same paragraph as having a housing 204 and that the drug reservoir is contained therein. The paragraph beginning at line 11 of page 12 has been amended to recite that the control circuitry may be contained within housing 204. Thus, it is respectfully submitted that the grounds for this objection have been cured and that the objection should be withdrawn.

The specification was objected to for failing to disclose delivering an electrical pulse with a pulse width of from about 50 ms to about 200 ms. As described above, claims 46 and 58 have been amended to recite 50 microseconds and 200 microseconds, which conforms with the disclosure at lines 6 and 7 of page 18 of the specification. Thus, it is respectfully submitted that the grounds for this objection have been cured and that the objection should be withdrawn.

The specification was objected to for failing to disclose conveying a biological parameter to the operative control circuitry. The paragraph beginning at line 24 of page 13 has been amended to disclose that the sensor circuitry provides a biological parameter to the operative control circuitry. Thus, it is respectfully submitted that the grounds for this objection have been cured and that the objection should be withdrawn.

The specification was objected to for failing to disclose a method for treating cancer with a wholly-implantable medical device and implanting a wholly-implantable electroporation device within a body. Claim 46 has been amended to delete references to an implantable medical device in the preamble, and claim 58 does not reference an implantable medical device. Further, the paragraph beginning at line 13 of page 10 has been amended to recite that cancer is treated using a wholly implantable medical device that is configured to deliver electroporation therapy. Thus, it is respectfully submitted that the grounds for this objection have been cured and that the objection should be withdrawn.

The specification has was objected to for failing to disclose at least one wholly-implantable lead and delivering a drug to a body via a fluid reservoir disposed within the wholly-implantable medical device. The paragraph beginning at line 10 of page 11 has been amended to disclose that the first lead 202 may be wholly implantable. Further, the paragraph beginning at line 16 of page 13 has been amended to disclose that the fluid reservoir is contained within the housing of the wholly-implantable medical device. Thus, it is respectfully submitted that the grounds for this objection have been cured and that the objection should be withdrawn.

Objections to the Claims

Claims 46 – 69 have been objected to because of various informalities. It is respectfully submitted that the grounds for the objections have been cured and that the objections should be withdrawn.

Claim 46 was objected to for reciting "said electrical pulse" without proper antecedent basis. Claim 46 has been amended to recite "said at least one electrical pulse". Thus, it is respectfully submitted that the grounds for this objection have been cured and that the objection should be withdrawn.

Claim 58 was objected to for reciting "the at least one wholly-implantable therapy electrode". Claim 58 has been amended to recite "at least one wholly-implantable

therapy electrode". Thus, it is respectfully submitted that the grounds for this objection have been cured and that the objection should be withdrawn.

Claim 58 was objected to for reciting "said pulse" without proper antecedent basis. Claim 58 has been amended to recite "said at least one electrical pulse". Thus, it is respectfully submitted that the grounds for this objection have been cured and that the objection should be withdrawn.

Claims 46 and 58 were objected to for a missing word. Claims 46 and 58 were amended to insert the word "strength" after the word "field" in each claim. Thus, it is respectfully submitted that the grounds for this objection have been cured and that the objection should be withdrawn.

Claim 58 was objected to for a missing word. The word "a" was added to recite "a wholly-implantable electroporation device". Thus, it is respectfully submitted that the grounds for this objection have been cured and that the objection should be withdrawn.

Rejections Under 35 U.S.C. § 112

Claims 53, 68 and 69 have been rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is respectfully submitted that the cancellation of claims 53, 68 and 69 has cured the grounds for this rejection, and that the rejection should be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 46 – 48, 50 – 53, 56 and 57 have been rejected under 35 USC § 102(e) as being anticipated by U.S. Patent No. 6,733,485 ("Whitehurst et al '485"). This rejection is respectfully traversed.

Claim 46 has been amended to incorporate the subject matter of canceled claim 49, which was not rejected under 35 USC § 102(e). Thus, it is respectfully submitted that claim 46, as amended, should not longer be rejectable under 35 USC § 102(e) as being anticipated by Whitehurst et al '485, and that the rejection should be withdrawn. The

rejection of claim 49 under 35 USC § 103(a), as such rejection applies to amended claim 46, will be addressed below.

Claims 47, 48, 50 – 53, 56 and 57 depend from claim 46, and as such incorporate all of the subject matter of claim 46, as amended. Because claim 46, as amended, is no longer rejectable under 35 USC § 102(e) as being anticipated by Whitehurst et al '485, it is respectfully submitted that claims 47, 48, 50 – 53, 56 and 57 are likewise no longer rejectable under 35 USC § 102(e), and that the rejection should be withdrawn.

Rejections Under U.S.C. § 103

Claim 49, as incorporated into claim 46

Claim 49 has been rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,733,485 ("Whitehurst et al '485") in view of U.S. Patent No. 6,120,493 ("Hofmann '493"). Due to the incorporation of the subject matter of claim 49 into claim 46, and the cancellation of claim 49, this rejection will be addressed as if it applied to claim 46, as amended. This rejection is respectfully traversed.

Whitehurst et al '485 discloses microstimulator-based electrochemotherapy methods and systems. A microstimulator 150 includes a reservoir 140 that contains fluids or drugs to be delivered to the patient, as well as electrical control circuitry 154 (column 11, lines 30 – 32, and column 13, lines 60 – 62). The fluid or drug may be delivered to a location in the patient via infusion outlets or catheters (column 12, lines 18 – 29). The fluid may be applied to the patient and an electrical pulse delivered over electrodes with a pulse width of 100 milliseconds, creating an electric field strength of 1300 V/cm (column 8, lines 12 – 14). But Whitehurst et al '485 does not show, disclose or suggest detecting a qRs complex from an electrocardiogram of the body and synchronizing the delivering of at least one electrical pulse with the qRs complex.

Hofmann '493 discloses a method for the introduction of therapeutic agents utilizing an electroporation apparatus. Needle electrodes, with hollow cores, are inserted into the tissue of the patient, and therapeutic substance delivered (column 9, lines 35 – 39). The electrodes are then pulsed in various patterns (column 12, lines 7 – 19 and

throughout the specification). Hofmann '493 describes various tests of the system performed on animal subjects (column 15, line 1 through column 20, line 47). As part of several of these tests, ECGs were taken in order to determine the impact of the electrical stimulation on the heart of the subject animal (see, e.g., column 17, lines 39 – 42). In the exemplary test, the QRS waves of the animal were observed to verify that they did not differ based on different patterns of electrical pulses and that there were no disturbances of the cardiac rhythm (column 17, lines 42 – 45). But Hofmann '493 does not show, disclose or suggest detecting a QRS complex and synchronizing the delivering of at least one electrical pulse with the QRS complex. Instead, Hofmann '493 discloses only that as part of a lab test on an animal the animal's QRS waves were observed to verify that there were no differences in the QRS waves from different pulse patterns, and that there were no disturbances of cardiac rhythm. Hofmann '493 does not show, disclose or suggest that electrical pulses are synchronized with a QRS complex.

By contrast, claim 46, as amended to incorporate the subject matter of claim 49, recites detecting a qRs complex from an electrocardiogram of the body and synchronizing the delivering of at least one electrical pulse with the qRs complex. This is manifestly different from the description of Hofmann '493, which described only observing the QRS complex of a test animal to determine whether the animal was suffering any adverse cardiac responses to the therapy. But Hofmann '493 does not show, disclose or suggest synchronizing any delivery of electrical pulses with a detected qRs complex.

Neither Whitehurst et al '485 nor Hofmann '493, alone or in combination, show, disclose nor suggest an essential element of claim 46, as amended. Thus, it is respectfully submitted that claim 46, as amended, is not rejectable under 35 USC § 103(a) as being unpatentable over Whitehurst et al '485 in view of Hofmann '493. The rejection of canceled claim 49 is moot.

Claims 47, 48, 50 – 52, 56 and 57 depend from claim 46, and as such incorporate all of the subject matter of claim 46, as amended. Because claim 46, as amended, is not rejectable under 35 USC § 103(a) as being unpatentable over by Whitehurst et al '485 in

view of Hofmann '493, it is respectfully submitted that claims 47, 48, 50 – 52, 56 and 57 are likewise not rejectable under 35 USC § 103(a).

Claims 54 and 55

Claims 54 and 55 have been rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,733,485 ("Whitehurst et al '485") in view of U.S. Patent No. 5,386,837 ("Sterzer '837"). This rejection is respectfully traversed.

The above discussion of Whitehurst et al '485 is incorporated in its entirety.

Sterzer '837 discloses a method for enhancing delivery of chemotherapy employing high-frequency force fields. A shock of high frequency pulsed wave energy is pulsed into the cells of tumor (column 3, lines 48 – 50). The high frequency energy causes the plasma membranes of the cells to break down, as part of increased temperature of surrounding cells, thereby allowing for increased efficiency of fluid transfer to the cells (column 3, lines 57 – 67). But Sterzer '837 does not show, disclose or suggest detecting a qRs complex from an electrocardiogram of the body and synchronizing the delivering of at least one electrical pulse with the qRs complex.

By contrast, as noted above, claim 46, as amended, from which claims 54 and 55 depend, recites detecting a qRs complex from an electrocardiogram of the body and synchronizing the delivering of at least one electrical pulse with the qRs complex. Neither Whitehurst et al '485 nor Sterzer '837 show, disclose or suggest detecting a qRs complex from an electrocardiogram of the body and synchronizing the delivering of at least one electrical pulse with the qRs complex.

Neither Whitehurst et al '485 nor Sterzer '837, alone or in combination, show, disclose or suggest an essential element of claim 46, as amended. Because claims 54 and 55 depend from claim 46, they incorporate all of the subject matter of claim 46, as amended. In addition, claims 54 and 55 recite additional patentable subject matter. Because claim 46, as amended, is not rejectable under 35 USC § 103(a) as being unpatentable over Whitehurst et al '485 in view Sterzer '837, and because of the additional patentable subject matter, it is respectfully submitted that the rejection of

claims 54 and 55 under 35 USC § 103(a) as being unpatentable over Whitehurst et al '485 in view Sterzer '837 is improper and should be withdrawn.

Claims 58, 59, 60, 63 – 65 and 67 - 69

Claims 58, 59, 63 – 65 and 67 – 69 have been rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,389,069 ("Weaver '069") in view of U.S. Patent No. 5,386,837 ("Sterzer '837"). Claim 60 has been rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,389,069 ("Weaver '069") in view of U.S. Patent No. 5,386,837 ("Sterzer '837") in further view of U.S. Patent No. 6,120,493 ("Hofmann '493"). These rejections are respectfully traversed.

The above discussions of Hofmann '493 and Sterzer '837 are incorporated in their entirety.

Weaver '069 discloses a method and apparatus for in vivo electroporation of remote cells and tissue. A rod with an electrode is inserted into tissue, while another electrode is affixed to the skin of the patient (column 3, lines 21 – 54). A needle is inserted into the tissue and a chemical agent is transmitted from a syringe (column 4, lines 14 – 22). A voltage is applied over the two electrodes to cause electroporation of the tissue (column 4, lines 36 – 40). However, Weaver '069 does not show, disclose or suggest detecting a qRs complex from an electrocardiogram of the body and synchronizing the delivering of at least one electrical pulse with the qRs complex.

By contrast, claim 58, as amended to incorporate the subject matter of canceled claim 60, recites detecting a qRs complex from an electrocardiogram of the body and synchronizing the delivering of at least one electrical pulse with the qRs complex. As has been discussed above, neither Weaver '069, Sterzer '837 nor Hofmann '493 show, disclose or suggest detecting a qRs complex from an electrocardiogram of the body and synchronizing the delivering of at least one electrical pulse with the qRs complex.

Neither Weaver '069, Sterzer '837 nor Hofmann '493, alone or in combination, show, disclose or suggest an essential element of claim 58, as amended. Thus, the rejection of claim 58, as amended, under 35 USC § 103(a) as being unpatentable over

Weaver '069 in view of Sterzer '837 is improper and should be withdrawn. Likewise, claim 58, as amended to incorporate the subject matter of claim 60, is not rejectable under 35 USC § 103(a) as being unpatentable over Weaver '069 in view of Sterzer '837 in further view of Hofmann '493.

Claims 59, 63 – 65 and 67 depend from claim 58 and as such incorporate all of the subject matter of claim 58, as amended. In addition, claims 59, 63 – 65 and 67 recite additional patentable subject matter. Because the rejection of claim 58, as amended, is improper, and because of the additional patentable subject matter, the rejection of claims 59, 63 – 65 and 67 under 5 USC § 103(a) as being unpatentable over Weaver '069 in view of Sterzer '837 is improper and should be withdrawn. In addition, claims 59, 63 – 65 and 67 are not rejectable under 35 USC § 103(a) as being unpatentable over Weaver '069 in view of Sterzer '837 in further view of Hofmann '493.

Claims 61, 62 and 66

Claims 61, 62 and 66 have been rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,389,069 ("Weaver '069") in view of U.S. Patent No. 5,386,837 ("Sterzer '837") in further view of U.S. Patent No. 6,733,485 ("Whitehurst et al '485"). These rejections are respectfully traversed.

The above discussions of Whitehurst et al '485, Sterzer '837 and Weaver '069 are incorporated in their entirety. None of these references show, disclose or suggest detecting a qRs complex from an electrocardiogram of the body and synchronizing the delivering of at least one electrical pulse with the qRs complex.

Claim 58, as amended, from which claims 61, 62 and 66 depend, recites detecting a qRs complex from an electrocardiogram of the body and synchronizing the delivering of at least one electrical pulse with the qRs complex. Thus, neither Whitehurst et al '485 nor Sterzer '837 nor Weaver '069, alone or in combination, show, disclose or suggest an essential element of claim 58, as amended. Because claims 61, 62 and 66 depend from claim 58, they incorporate all of the subject matter of claim 58, as amended. In addition, claims 61, 62 and 66 recite additional patentable subject matter. Because claim 58, as

amended, is not rejectable under 35 USC § 103(a) as being unpatentable over Weaver '069 in view of Sterzer '837 in further view of Whitehurst et al '485, and because of the additional patentable subject matter, it is respectfully submitted that the rejection of claims 60, 61 and 66 under 35 USC § 103(a) as being unpatentable over Weaver '069 in view of Sterzer '837 in further view of Whitehurst et al '485 is improper and should be withdrawn.

Summary

In view of the amendments and arguments presented, claims 46 – 48, 50 – 52, 54 – 59 and 61 – 67 should be allowable. This application should be in condition for allowance and a notice to that effect is earnestly solicited.

Correspondence

All correspondence should continue to be directed to:

Medtronic, Inc.
710 Medtronic Parkway NE
Minneapolis, MN 55432-9924.

Respectfully Submitted,

BOZIDAR FEREK-PETRIC

Date: August 21, 2008

William D. Bauer
Registration No. 28,052

IPLM Group, P.A.
Broadway Place West, Suite 6600
1300 Godward Street NE
Minneapolis, Minnesota 55413-1741
Telephone: 612-331-7405
Facsimile: 612-331-7401